REMARKS/ARGUMENTS

Claims 18, 41 and 46-85 were pending in this application.

Claims 41, 46, 50-54, 60, 62, 68, 78 and 84 have been currently amended and claims 86-104 have been newly added. Support for the claim amendments can be found throughout the application as filed. Specifically, support can be found at page 6, lines 12-20; page 13, lines 13-15 and page 16, lines 28-31 continuing on page 17, lines 1-12. It is submitted that no new matter has been added.

Claims 58, 66, 70-77, 82 have been cancelled without waiver or prejudice. Applicants reserve the right to pursue the inventions claimed therein in this or future applications.

Thus, claims 18, 41, 46-69 and 78-104 are currently pending in this application.

Applicants acknowledge that the following previous objections and rejections are withdrawn by the Examiner in light of the Amendment filed in Paper No. 15, on June 9, 2003: (i) the objection to the specification; (ii) the objection to claims 18 and 41; (iii) the rejection of claim 18 under 35 U.S.C. § 112, first paragraph; and (iv) the rejection of claim 18 under 35 U.S.C. § 102(b) as being anticipated by Hopp et al. (U.S. Patent No 5,011,912) (*see*, Office Action, page 2, section 1).

I. Amendments to the Specification

The specification has been amended to correct minor typographical errors on pages 6 and 7. It is submitted that no new matter has been added.

II. Previously Applied Rejections

(a) Claim 41 stands rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,248,714 (*see*, Office Action, page 2, section 3a).

Applicants aver that claim 1 of U.S. Patent No. 6,248,714 relates to the use of soluble IL-13 receptor proteins to inhibit IL-13 function. These soluble receptors function by binding IL-13 ***protein*** or biological variants thereof, thereby preventing IL-13 from binding to the native IL-13 receptor on the cell surface. In striking contrast, Applicants' claimed invention is directed to antibodies that bind IL-13. Such antibodies can inhibit IL-13 function by ***binding to the receptor*** and blocking access to IL-13 or biological variants thereof to bind the wild type receptor. Thus, Applicants submit that the invention in U.S. Patent No. 6,248,714 does not render obvious Applicants' claimed invention. Accordingly, Applicants respectfully request that this rejection be withdrawn.

(b) The Examiner has rejected claims 18 and 41 under 35 U.S.C. § 112, second paragraph, for use of the term "specifically" (Office Action, page 2, section 3b). Support for the term "specifically" can be found at page 16, line 29 of the application as filed. Applicants respectfully submit that the antibody field is highly developed, mature art area and that one of ordinary skill in the art would comprehend the term "specifically" as recited in claims 18 and 41. The Examiner is reminded that a patent need not teach and preferably omits what is well known in the art (*In re Buchner*, 929 F.2d 660,661, 18USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987)). Based on the foregoing arguments, Applicants aver that the grounds for the rejection of claims

18 and 41 under 35 U.S.C. § 112, second paragraph, have been overcome. Accordingly, Applicants respectfully request that this rejection be withdrawn.

III. Rejection under 35 U.S.C. § 112, first paragraph

Claims 46-85 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly not enabling the claimed invention (Office Action, page 3, section 4). Specifically, claims 46, 54 and claims depending therefrom were rejected for allegedly possessing undue breadth (Office Action, page 3, last paragraph). Claims 50, 52, 58, 60, 66, 68, 74, 76, 82 and 84 were rejected for purportedly not enabling the treatment of cancer (Office Action, page 4, first full paragraph). Claims 62, 70 and 78 were rejected for allegedly being "overly broad for reciting an antibody that binds to a 'biologically active fragment' or to a 'variant' of IL-13-bc" (Office Action, page 5, first full paragraph). Finally, claims 62-85 were rejected for allegedly lacking adequate written description (Office Action, page 6, section 4b).

Claims 58, 66, 70-77 and 82 have been cancelled. Thus, this rejection as it applies to these claims has been rendered moot.

Enablement Rejections

Claims 46 and 54 have been amended to recite that the IL-13bc protein comprises an amino acid sequence selected from the group consisting of the amino acid sequence of SEQ ID NO: 4; the amino acid sequence of SEQ ID NO: 4 from amino acids 26 to 341; and the amino acid sequence of SEQ ID NO: 4 from amino acids 363 to 380. The Examiner has acknowledged that the specification enables an antibody that binds an IL-13bc protein defined in the manner described above (*see*, Office Action, page 4). Thus, Applicants aver that the grounds for this rejection have been overcome. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Claims 50, 52, 58, 60, 66, 68, 82 and 84 have been amended to delete cancer from the list of recited diseases. The Examiner has acknowledged that methods of treating all the other recited diseases in the above-listed claims are enabled (Office Action, page 4). Accordingly, with the entry of the instant amendment, Applicants respectfully request that this rejection be withdrawn.

Regarding the rejection of claim 62 and claims depending therefrom, Applicants respectfully assert that these claims are fully enabled. At the outset, it should be noted that claim 62 has been amended to recite, in relevant part, "wherein said fragment of IL-13bc binds to IL-13 or a biologically active fragment thereof." The specification clearly describes how to determine whether a fragment of IL-13bc binds IL-13 (see page 11, lines 12-20). The specification further elaborates that it is preferred that the biological activity possessed by the protein is the ability to bind IL-13 or a fragment thereof and that preferably the K_D is about 0.1 to about 100nM (*see*, page 7, lines 12-21). In addition, the specification clearly identifies the extracellular domain of IL-13bc (amino acids 26-341) that comprise the amino acids involved in IL-13 binding (see, page 6, lines 16-20). Furthermore, Examples 3-5 of the application (pages 22-25) provide sufficient guidance to determine whether a fragment of IL-13bc can bind IL-13 or a fragment thereof. Taken together, Applicants aver that claim 62 and claims depending therefrom are fully enabled. The ground for this rejection having been overcome, Applicants respectfully request that this rejection under 35 U.S.C. § 112, first paragraph, be withdrawn and the application reconsidered.

Regarding the rejection of claim 78 and claims depending therefrom for allegedly being non-enabling (Office Action, pages 5-6), Applicants respectfully assert that these claims are fully enabled.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976). The quantity of experimentation needed to be performed by one skilled in the art is only one factor involved in determining whether "undue experimentation" is required to make and use the invention. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the skilled artisan is given sufficient direction or guidance. Time and difficulty of experiments are not determinative if they are merely routine.

Claim 78 has been currently amended to specifically cover antibodies that bind to IL-13bc variants that are encoded by nucleic acid sequences which hybridize to the nucleotide sequence set forth in SEQ ID NO:3 under highly stringent conditions, wherein said nucleic acid sequence encodes a protein that binds to IL-13 or a biologically active fragment thereof. Thus, unlike the Examiner's assertion, the scope of claims 78 and claims depending therefrom are not practically infinite; instead, the scope of these claims is limited to antibodies that bind to IL-13bc variants that can in turn bind to IL-13. Additionally, the application provides sufficient guidance to identify the IL-13bc variants recited in claim 78. Specifically, methods of hybridization of nucleic acids under highly stringent conditions are well known in the art (*also see* page 8, line 2 of application), while methods to determine whether a protein can bind IL-13 is described in detail in Examples 2-5 of the application (*see* pages 19-25). Furthermore, it was well known that antibodies could be made against virtually any protein and the level of skill and knowledge in the art of antibodies at the time of filing was high. Taken together, Applicants aver that this ground of rejection has been overcome and respectfully request that the rejection be reconsidered and withdrawn.

Written Description Rejections

Claims 62 and claims depending therefrom were rejected for purportedly lacking adequate written description (Office Action, page 6, section 4b). Applicants respectfully traverse this rejection.

An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000).

In the instant invention, the specification clearly defines what is meant by "wherein said fragment of IL-13bc binds to IL-13 or a biologically active fragment thereof" (*see*, above) and Examples 3-5 provide written description support to identify such fragments of IL-13bc. Furthermore and importantly, the specification provides guidance as to where to obtain such fragments since it discloses the amino acids that comprise the extracellular domain of IL-13bc (page 6, lines 17-18), which is the domain that binds IL-13 as shown in Examples 2-5 (pages 22-25). Thus, contrary to the Examiner's position, the specification does disclose a structure for the fragment of claim 62, namely the extracellular domain of IL-13bc, amino acids 26-341 of SEQ ID NO.4, and provides evidence that this domain can bind IL-13. Thus, based on this disclosure, a skilled artisan would have understood that the inventor was in possession of the claimed invention at the time of the filing. Accordingly, Applicants aver that the ground for this rejection has been overcome and request that this rejection be withdrawn.

Claims 78 and claims depending therefrom stand rejected as not satisfying the written description requirement (Office Action, page 6, section 4b). Applicants respectfully traverse this rejection.

Independent claim 78 is drawn to antibodies that bind IL-13bc variant proteins which are encoded by nucleic acid sequences which hybridize under highly stringent conditions to SEQ ID NO:3, wherein said nucleic acid sequences encode proteins that bind to IL-13 or biologically active variants thereof. A person of skill in the art would not expect substantial variation among species encompassed within the scope of these claims because the highly stringent hybridization conditions set forth in the claim would yield structurally similar DNAs and consequently structurally similar proteins. Thus, a representative number of species is disclosed, since highly stringent hybridization conditions in combination with the coding function of DNA (encoding a protein that binds to IL-13 or a biologically active fragment thereof) and the level of skill and knowledge in the art are adequate to determine that the applicant was in possession of the claimed invention. Taken together, Applicants respectfully assert that the grounds for this rejection have been overcome. Accordingly, it is requested that this rejection be reconsidered and withdrawn.

IV. Rejection under 35 U.S.C. § 112, second paragraph

(a) Claims 50, 52, 58, 60, 66, 68, 74, 76, 78, 82 and 84 stand rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite for reciting the term "modulating" (Office Action, page 9, section 5a).

Claims 58, 66, 70-77 and 82 have been cancelled. Thus, this rejection as it applies to those claims has been rendered moot.

Claims 50, 52, 60, 68 and 84 have been amended to replace the term "modulating" with "inhibiting."

With the instant amendment to the claims, Applicants believe that this rejection under 35 U.S.C. § 112, second paragraph has been rendered moot. Thus, Applicants request that this rejection be withdrawn and the application reconsidered.

(b) Claim 51 stands rejected under 35 U.S.C. § 112, second paragraph, for omitting the term "composition" (Office Action, page 9, section 5b). Claim 51 has been amended to recite "composition."

With the instant amendment to the claims, Applicants believe that this rejection under 35 U.S.C. § 112, second paragraph has been rendered moot. Thus, Applicants request that this rejection be withdrawn and the application reconsidered.

V. Conclusion

Applicants believe that all of the outstanding rejections of record have been overcome by amendment and/or argument. Accordingly, the claims are now believed to be in condition for allowance. Applicants respectfully request that the Examiner issue a timely Notice of Allowance.

Applicants petition for a ***two-month*** extension of time to respond to the Office Action mailed August 18, 2003. Please charge any payments due to our Deposit Account No. 08-0219. No additional fees are believed to be due in connection with this correspondence. However, if any fees are due, please charge any payments due or credit any overpayments to our Deposit Account No. 08-0219.

The Examiner is invited to telephone the undersigned at the telephone number given below in order to expedite the prosecution of the instant application.

Respectfully submitted,

Dated: January 16, 2004

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